FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
Psychopharmacologic Drugs Advisory Committee Meeting
The Great Room, White Oak Conference Center, Food and Drug Administration Campus
September 16, 2010

AGENDA

The committee will discuss the available safety and efficacy data for supplemental new drug application (sNDA) 21-897/015, VIVITROL (naltrexone for extended-release injectable suspension) sponsored by Alkermes, Inc., for the treatment of opioid dependence.

8:30 a.m.	Call to Order Introduction of Committee	**Susan Schultz, M.D.** Acting Chair Psychopharmacologic Drugs Advisory Committee (PDAC)
	Conflict of Interest Statement	**Yvette W. Waples, Pharm.D.** Designated Federal Official PDAC
8:40 a.m.	Opening Remarks	**Celia Winchell, M.D.** Clinical Team Leader Division of Anesthesia and Analgesia Products (DAAP), Office of Drug Evaluation (ODE) II, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER) Food and Drug Administration (FDA)
8:50 a.m.	**SPONSOR PRESENTATION** Introduction	**Elliott Ehrich, M.D**. Chief Medical Officer and Senior Vice President of Research and Development Alkermes, Inc.
	Opioid Dependence and Naltrexone Overview	**Charles P. O'Brien, M.D., Ph.D.** Kenneth Appel Professor and Director of the Center for Studies of Addiction Department of Psychiatry University of Pennsylvania School of Medicine
	Review of Efficacy	**Elliott Ehrich, M.D.** Alkermes, Inc.
	Review of Safety	**Bernard L. Silverman, M.D.** Vice President, Clinical Science Alkermes, Inc.
	We Need Treatment Options	**Paul Earley, M.D.** Addiction Medicine Physician Medical Director of the Talbott Recovery Center
	Closing Remarks	**Elliott Ehrich, M.D., Alkermes, Inc.**

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
Psychopharmacologic Drugs Advisory Committee Meeting
The Great Room, White Oak Conference Center, Food and Drug Administration Campus
September 16, 2010

AGENDA

-continued-

9:50 a.m.	Clarifying Questions	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATION**	
	Presentation of Safety of Vivitrol For Opioid Dependence	**Rachel Skeete, M.D.** Clinical Reviewer DAAP, ODE II, OND CDER, FDA
	Summary of Clinical Pharmacology of Vivitrol	**Srikanth C. Nallani, Ph.D.** Clinical Pharmacology Reviewer Office of Clinical Pharmacology Office of Translational Science (OTS) CDER, FDA
	Presentation of Efficacy of Vivitrol For Opioid Dependence	**Feng Li, Ph.D.** Biostatistics Reviewer Division of Biometrics (DB) II, Office of Biostatistics (OB), OTS, CDER,FDA
11:15 a.m.	Summary of Clinical Site Inspections	**Tejashri Purohit-Sheth, M.D.** Branch Chief, Good Clinical Practice II Division of Scientific Investigations Office of Compliance CDER, FDA
11:30 a.m.	Dealing with Foreign Clinical Trial Data in the Review Process: Some Experience and the Role of The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: Ethnic Factors in the Acceptability of Foreign Clinical Data (ICH E5) Guidance	**Robert O'Neill, Ph.D.** Director, OB, OTS, CDER, FDA
12:00 p.m.	Clarifying Questions	
12:15 p.m.	**LUNCH**	
1:15 p.m.	Open Public Hearing	
2:15 p.m.	Charge to the Committee	
2:20 p.m.	Panel Discussion and Questions to the Committee	
3:00 p.m.	**BREAK**	
3:15 p.m.	Panel Discussion and Questions to the Committee	
5:00 p.m.	**ADJOURN**	